THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:
	: Examiner: I. A. Greene
Ijeoma UCHEGBU et al.	:
	: Group Art Unit: 1619
Application No. 10/528,602	:
	: Attorney Docket No.: 4938-P03603US00
Filing Date: September 29, 2005	:
	: Confirmation No. 3999
For: DRUG DELIVERY	:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO OFFICIAL COMMUNICATION
CONCERNING PREVIOUSLY FILED
TRAVERSAL AND REQUEST FOR RECONSIDERATION
OF REQUIREMENT FOR RESTRICTION

Dear Sir:

In reply to the official communication dated April 16, 2009, applicants reiterate their traversal of the requirement for restriction set forth in the January 27, 2009 Official Action in the above-identified patent application, and once again request reconsideration thereof.

In the January 27, 2009 Official Action, the examiner required restriction based on the assessment that the pending claims are directed to three (3) allegedly separate, patentably distinct inventions, as set out at page 2 of the Official Action. This restriction requirement is plainly improper for failure to comply with the relevant provisions of the Manual of Patent Examining Procedure (MPEP) pertaining to unity of invention determinations.

The present application was filed under 35 USC §371 as a U.S. national stage application under the Patent Cooperation Treaty (PCT).

As stated in 1893.03(d) of the MPEP:

> Examiners are reminded that unity of invention (not restriction practice . . .) is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 USC 371 . . .
>
> The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. . . . The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.
>
> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art . . .

In the present case, the subject matter of claims 1-3, 32, 33, 44 and 46-48 has a substantial structural feature in common, namely, the monomeric subunits that make up the claimed polyethylenimine polymer. The claimed polymers also have a common utility in that they enable the delivery of poorly soluble drugs, such as cyclosporin. In view of this common structural feature and common utility, the subject matter of Groups I-III clearly constitutes a single inventive concept, and has unity of invention.

Moreover, given the substantial structural feature which the claimed subject matter has in common, it appears that the examiner's search, at least with respect to the Group I and III claims, would of necessity cover overlapping art areas. It is noteworthy in this regard that the examiner has failed to assert separate classification as warranting the present restriction requirement. Thus, the concurrent examination of all of the Group I and III claims in the present application should not materially affect the examiner's workload.

Furthermore, notwithstanding the prospect for later rejoinder, the process claimed in the group II claims should also be examined together with the polymers and compositions of Groups I and III, in view of the examiner's failure to make the showing required in MPEP §806.05(f) with respect to patentable distinctness of claims to a product and process of making same.

The impropriety of this restriction requirement is underscored by the fact that there was no lack of unity objection during the international stage of this application. Rather, the subject matter of all of the claims was regarded as a single inventive concept, as evidenced by the treatment of the claims in the International Search Report (copy attached). Apparently, the International Searching Authority (ISA) does not share the examiner's view that the polymer formula of claim 1 lacks unity of invention *a priori*. Given that there was no lack of unity objection by the ISA, it necessarily follows that the present claims satisfy the unity of invention standards of the PCT.

As the January 27, 2009 Official Action fails to comply with the established U.S. Patent and Trademark Office unity of invention guidelines, as demonstrated above, it is respectfully submitted that this restriction requirement be reconsidered and withdrawn.

In order to be fully responsive to the above-mentioned restriction requirement, applicants provisionally elect for examination in this application the subject matter of Group III, i.e., claims 44 and 46-48 drawn to a pharmaceutical composition comprising a polyethylenimine.

As for the election of species requirement, applicants elect the polymer species QCPEI 2 described, *inter alia,* in Examples 1 and 2 of the present specification. Attachment A shows the structure of the elected species. Claims 1-3, 32, 33, 44 and 46-48 are believed to read on the elected species.

The currently elected species is encompassed by the genus of polyethylenimine polymers recited in claim 1. It is respectfully submitted that the examiner is mistaken in asserting that the α subunit of the polymer must be present. Claim 1 expressly recites that "α is between 0 to

90%". The only other claim recitation relating to the presence of the α subunit is that "α+β+γ=100%". By way of example, in the event β is 50% and γ is 50%, it necessarily follows that the α subunit is absent. There are numerous other conceivable examples in which the α subunit is also absent. Thus, the present election of species cannot be faulted because there is no α subunit present therein. The β and γ subunits of the elected species plainly conform to the recitations of claim 1, wherein the "Z" groups are defined as ". . . independently hydrogen or any linear or branched, substituted or unsubstituted or cyclo form of any hydrophobic substituent . . ."

Applicants' provisional election in response to the present restriction requirement and their species election are without prejudice to their right to file one or more divisional applications, as provided in 35 USC §121, on the subject matter of any claims finally held withdrawn from consideration in this application.

Claim 1 will be amended in due course, such that the polymer formula set forth therein includes a positive charge on the quaternized nitrogens shown in the β and γ subunits.

This reply is being filed within the response period specified in the April 16, 2009 official communication.

Early and favorable action on the merits of this application is respectfully requested.

Respectfully submitted,

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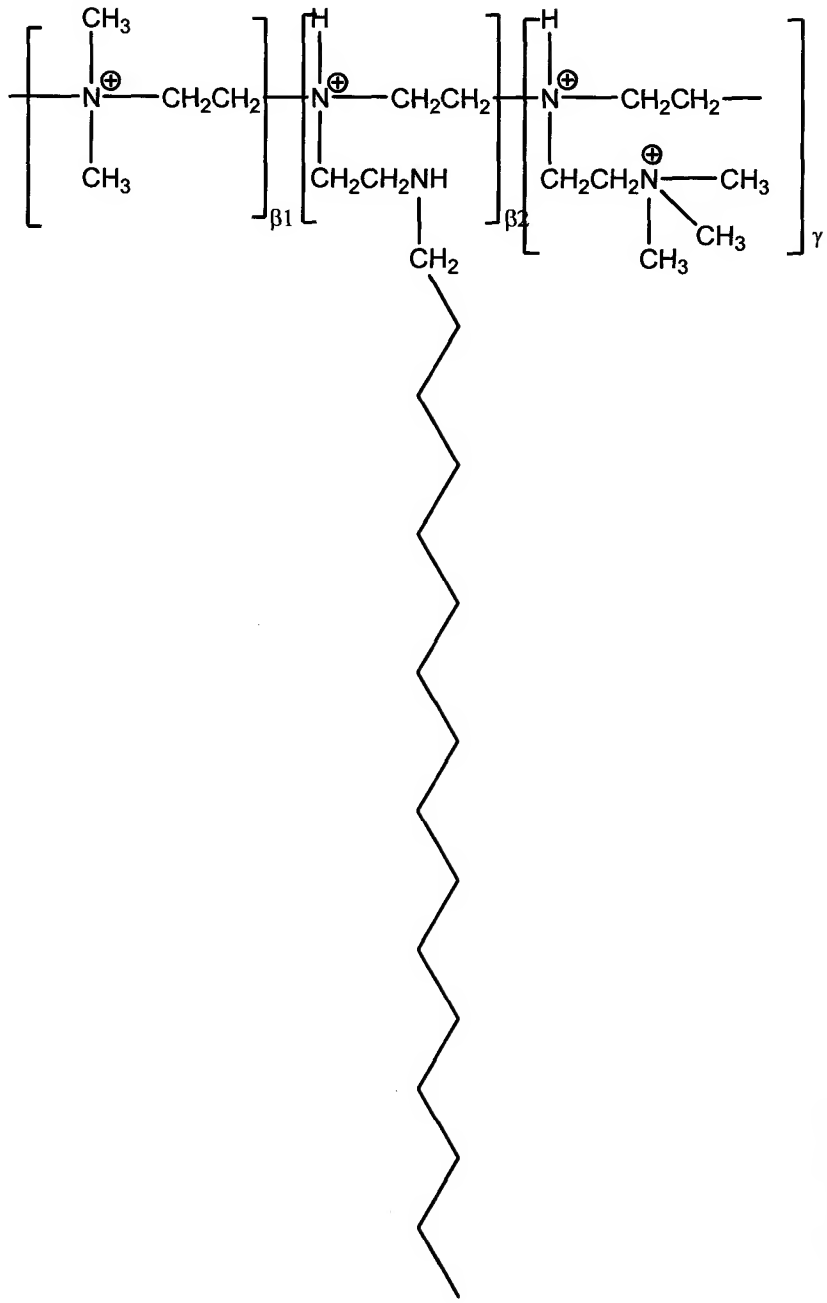
1. Attachment A: Structure of polymer species QCPEI2
2. Copy of International Search Report



$\beta 1 \sim 138$
$\beta 2 \sim 12$
$\gamma \sim 35$
In $\beta 1$, $Z = CH_3$

In $\beta 2$, $Z = CH_2CH_2NH(CH_2)_{15}CH_3$
In $\beta 2$, $Z = H$

In γ, $Y = N(CH_3)_3$
In γ, $Z = H$

ATTACHMENT A